REMARKS

Claim 1 has been amended, and new claim 51 has been added. Claims 1-29, 34-36 and 51 are presently pending in the application.

The Office Action rejected claims 1, 2, 4, 5, 14-17, 21, 22 and 34-36 under 35 U.S.C. 102(b) as allegedly being anticipated by Arm et al. (WO 93/20859). The Office Action also rejected claims 1, 4, 7-18, 21 and 22 under 35 U.S.C. 103(a) as allegedly being unpatentable in view of Hossainy et al. (U.S. Patent No. 6,451,373), rejected claims 1-6 and 21-29 under 35 U.S.C. 103(a) as allegedly being unpatentable over Ledergerber et al. (U.S. Patent No. 4,955,907) in view of Calhoun et al. (U.S. Publication No. 2002/0001609), and further rejected claims 1, 4, 7, 13-23, 25 and 29 under 35 U.S.C. 103(a) as allegedly being unpatentable over Lahtinen et al. (U.S. Publication No. 2003/0059463). Applicants respectfully traverse these rejections, for the following reasons.

Regarding these rejections, page 3 of the Office Action states that Arm et al. is silent in regard to the film characteristic being nonporous. In response, Applicants would like to direct the Examiner's attention to page 11 of the Arm et al. disclosure which appears to indicate carriers of that invention being capable of performing one or more of enhancing polymer degradation, creating pores in the film, and reducing absorption of the growth factor. That same page also states that the Arm et al. films are designed to promote tissue growth or infiltration, the latter term implying pores. In contrast, the currently claimed invention of Applicants is directed to, among other things, membranes that are substantially non-porous.

In connection with the Office Action's recitation of the Manual of Patenting Procedure (MPEP) Section 2111.03 [R-3] and decision to treat Applicants' "consisting essentially of" language as "comprising," Applicants respectfully submit that this decision would appear to been rendered in error.

Applicants would like to direct the Examiner's attention to various passages in Applicants' specification which emphasize an aspect of the current invention in which the membranes comprise a layer of polymer base material selected from the group consisting essentially of a lactide polymer and a copolymer of two or more cyclic esters. Applicants' Background of the

Invention section, for example, states that "[o]ne approach to the problem of adhesion has been the use of bioresorbable barrier materials, in the form of ... coatings, ... films, and the like, that are placed between a healing post-surgical site and adjacent surrounding tissue." Clearly, Applicants' presently claimed invention is not directed to such a broad concept as any and all bioresorbable coatings on implants.

Applicants' Background of the Invention section, furthermore, references several prior-art disclosures, one of them being U.S. Patent No. 6,153,252, which is a Syed F.A. Hossainy patent (cf. the current 103(a) rejection) and which is characterized as disclosing "[a]n exemplary method for coating a stent" to address "the problem of foreign body reactions ... by applying biocompatible polymeric coatings to ... stents." Such prior-art devices are distinguished from the currently claimed invention, as a result of, among other things, the prior-art devices taking too long to resorb, being insufficiently malleable, or requiring complex chemical formulations and/or reactions which may increase the cost of manufacturing.

The second paragraph in Applicants' Summary of the Invention section describes membranes according to an aspect of the current invention as tissue-reduction barrier membranes which are constructed entirely of resorbable polymers, and which can be selected from the group consisting of lactide polymers (e.g., copolymers) of two or more lactides.

Reducing tissue growth (i.e., scars or adhesions) is disclosed throughout Applicants' application as a focus of the invention.

The Incorporation of a growth factor, such as disclosed, for example, by Arm et al., into a membrane of the present invention would actually work to encourage tissue growth, rather than to impede it. Consequently, inclusion of a growth factor into Applicants' membranes would appear to materially affect (e.g., contradict) a basic or novel characteristic of the instant invention as set forth in claim 1.

Applicants respectfully submit that, even before the entering of the current amendment, the claims were sufficiently supported with emphasis in the specification to fully meet the requirements of the relevant patent case law for use of the "consisting essentially of" language and its intended meaning. Accordingly, it is Applicants' opinion the interpretation by the Office Action to treat this language as carrying a meaning of "comprises" was not properly imposed by

the Office Action. In an effort to expedite the prosecution of the present application, Applicants have amended the current independent claim 1, not so much as to overcome the rejections, but rather to further define one or more aspects of the present invention. For example, parts of claim 1 now correspond with language in the specification describing scar tissue-reduction barrier membranes as being constructed entirely of resorbable polymers which can be, for instance, selected from the group consisting of lactide polymers (e.g., copolymers) of two or more lactides.

Concerning the Office Action's contention that page 3, line 36 and 37, and page 4, lines 1-8, of Arm et al. teach a film of 100% polylactic acid (wherein the addition of a carrier and peptide growth factor to that film is allegedly disclosed as just a preferred embodiment, and not required), Applicants must respectfully disagree.

Regarding the reasoning for Applicants' disagreement, it should be noted that page 3, lines 33-35 of Arm et al. initially describe "sustained release compositions for the therapeutic delivery of polypeptide growth factors," and, then, the next lines 36 and 37 follow-up by further describing "The compositions" (emphasis added) as being biodegradable. That is, those lines 36 and 37 are not describing just any compositions, or compositions in general, but, rather, are specifically referencing back to and further describing "the" compositions that were just referenced in the preceding lines 33-35. Now, the compositions of the Arm et al. invention are described in those lines 36 and 37 as being "for the therapeutic delivery of polypeptide growth factors." Of course, in order to deliver the growth factors, the films of Arm et al. would appear, in the context of that invention, to need to contain the growth factors.

The following page 4, lines 1-8 of Arm et al., also relied upon by the Office Action in making its allegation that Arm et al. teaches a 100% polylactic acid film, describes the film of that invention as containing a copolymer, one or more polypeptide growth factors, and a carrier.

Furthermore, in connection with the Office Action's statement that "Arm et al. does in fact also disclose the production of 100% polylactic acid film...." Applicants add, however, that this construction is not regarded by that disclosure as useful and, to the contrary, is characterized on more than one occasion in the in Arm et al. disclosure as a "sham" (cf. page 18, line 32 and page 19, line 17).

It should be reiterated, concerning the Arm et al. reference, that the first paragraph of the Detailed Description section of that reference limits the disclosure and teaching to "compositions ... in the form of biodegradable polyester films ..., one or more peptide growth factors, and a carrier ...."

The Arm et al. references actually teaches away from use of a 100% polylactic acid film coating on an implant, because, according to Arm et al., such structure will not work.

Moreover, to the extent one of the growth-factor films of Arm et al. were to be provided on an implant (e.g., a screw), that film would actually work to encourage tissue growth, rather than to impede it as indicated by the currently claimed method steps of the invention.

Applicants request that the Examiner kindly elucidate paragraph 2 on page 6 of the Office Action, and, also, provide a citation to the relevant or governing MPEP section in the course of his undertaking such action.

On the rejection based upon Lahtinen, the Examiner provides, as a motivation to combine, a statement that "[o]ne would have been motivated to use polylactic acid as the polymer base coating for vascular graft because Lahtinen makes polylactic acid a preferred embodiment for coating a vascular graft. (See paragraph 135)." Applicants respectfully disagree. To the contrary, while paragraph 135 of Lahtinen does, indeed, mention polylactic acid and polyglycolic acid, it states that such materials may be used to "deliver the gene composition and also provide a surface for new endothelium growth...[acting as] scaffold[s] through which endothelial cells [may] migrate." (Emphasis added, to indicate composition and porous structure.) Accordingly, Lahtinen does not appear to disclose or suggest membranes which (1) comprises a layer of polymer base material selected from the group consisting essentially of a lactide polymer and a copolymer of two or more cyclic esters and which (2) are substantially non-porous. The Examiner in the rejection based upon Lahtinen continued, stating that "if one desired to utilize a vasculature coated graft, a skilled artisan would utilize a polylactic acid polymer base coating suggested by Latinen." However, even assuming, arguendo, such a statement to have merit, such a coating would not lead one skilled in the art to Applicants' claimed invention.

The Examiner in the rejection based upon Lahtinen further stated that "one would also be motivated to form a nonporous polymer film because Lehtinen teaches that a nonporous film 'serves to provide tear resistance.'" However, it is respectfully submitted that the reference's disclosed function of providing a surface acting as a scaffold through which endothelial cells [may] migrate for new endothelium growth would be more important than preventing tearing, so that one skilled in the art would not interpret paragraph 135 of Lahtinen as encompassing nonporous polylactic acid films.

In view of these and potentially other reasons, Applicants disagree with the Examiner's position that the instantly claimed method of attenuating adhesions between an implant and surrounding tissues would have been obvious.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 102 and 103. Applicants submit that the application is now in condition for allowance, and an early indication of same is requested. The Examiner is invited to contact the undersigned with any questions.

Respectfully submitted,

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